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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : Wolfgang Baiker) Art Unit: 1617
U.S. Appln. No. : 10/816,414) Examiner:
Confirmation No. : 8843
U.S. Filing Date : April 1, 2004
Title of Invention : Pharmaceutical combination for treating benign prostatic hyperplasia or
for treating abacterial prostatitis
Attny. Docket No.: 1/1454

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

February 11, 2005

TRANSMITTAL LETTER FOR INFORMATION DISCLOSURE STATEMENT

Sir:

Transmitted herewith concerning the subject application is an Information Disclosure Statement (Form 1449A/B) under 37 C.F.R. §§1.56 and 1.97, as more specifically described hereinbelow.

☒ 1.97(b). This Statement is being filed: i) within three (3) months of the filing date of a national application other than a continued prosecution application under 33 C.F.R. §1.53 (d); ii) within three (3) months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in an international application; iii) before the mailing of a first Office action on the merits; or iv) before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. §1.114.

☐ 1.97(c). This Statement is being filed after the time period specified in 37 C.F.R. §1.97(b), but before the mailing date of: i) a final action under 37 C.F.R. §1.113, ii) a notice of allowance under 37 C.F.R. §1.311, or iii) an action that otherwise closes prosecution in the application. This Statement is being accompanied by:

☐ A statement as specified in 37 C.F.R. §1.97(e) [see below]; or

☐ The fee set forth in 37 C.F.R. §1.17(p).

☐ The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No. 02-2955.

☐ 1.97(d). This Statement is being filed after the period specified in 37 C.F.R. §1.97(c) but on or before payment of the issue fee. This Statement is accompanied by a statement as specified in 37 C.F.R. §1.97(e) [see below] and the fee set forth in 37 C.F.R. §1.17(p).

☐ 1.97(e).

☐ Each item of information contained in the instant information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of the instant information disclosure statement; or

☐ No item of information contained in the instant information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in the instant information disclosure statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three (3) months prior to the filing of the instant information disclosure statement.

☐ The fee set forth in 37 C.F.R. §1.17(p).

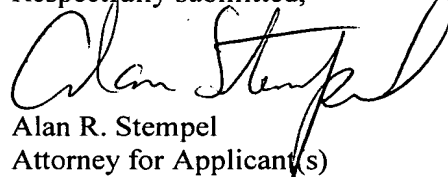
☐ The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No. 02-2955.

☐ 1.704(d). Each item of information contained in the accompanying information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, which communication was not received by any individual designated in section 1.56(c) more than thirty (30) days prior to the filing of the accompanying information disclosure statement.

☒ The Commissioner is hereby authorized to charge payment of any additional filing fees required under 37 C.F.R. §1.16 and any patent application processing fees under 37 C.F.R. §1.17, or credit any overpayment of same, to Deposit Account No. 02-2955.

Triplicate copies of this form are enclosed.

Respectfully submitted,



Alan R. Stempel
Attorney for Applicant(s)
Reg. No. 28,991

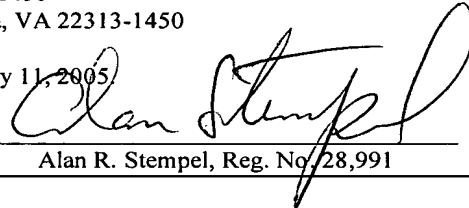
Patent Department
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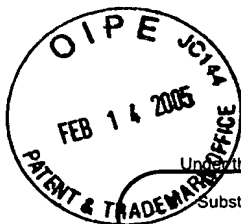
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Alan R. Stempel, Reg. No. 28,991



PTO/SB/08a (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

1

of

2

Complete if Known

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|------------------------|-----------------|
| Application Number | 10/816,414 |
| Filing Date | April 1, 2004 |
| First Named Inventor | Wolfgang Baiker |
| Art Unit | 1617 |
| Examiner Name | To be assigned |
| Attorney Docket Number | 1/1454 |

U. S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|-----------------------|--------------------------|--|--------------------------------|--|---|
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FOREIGN PATENT DOCUMENTS

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|-----------------------|--------------------------|---|--------------------------------|--|---|----------------|
| | | Country Code ³ Number ⁴ Kind Code ⁵ (if known) | | | | |
| | | WO 2004/026116 A2 | 04/01/2004 | The Regents of the Univ. of CA | | |
| | | DE 10024752 A1 | 11/29/2001 | Ben Pfeifer | | |
| | | EP 0034432 A2 | 08/26/1981 | Yamanouchi Pharmaceuticals | | |
| | | FR 2437838 | 04/30/1980 | Roecar Holdings | | |
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| | | | | Application Number | 10/816,414 |
| | | | | Filing Date | April 1, 2004 |
| | | | | First Named Inventor | Wolfgang Baiker |
| | | | | Art Unit | 1617 |
| | | | | Examiner Name | To be assigned |
| Sheet | 2 | of | 2 | Attorney Docket Number | 1/1454 |

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| | | DELLABELLA M.D. ET AL; Conservative management of juxtavesical calculi with Tamsulosin; European Urology Supplements February 1, 2003 Vol. 2 No. 1 page 81; Issn No. 1569-9056 | |
| | | GURUNADHA RAO TUNUGUNTALA H.S. ET AL; Management of Prostatitis; Prostate Cancer and Prostatic Diseases (2002) Vol. 5 No. 3 pages 172-179; Nature Publishing Group | |
| | | WAGENLEHNER F.M.E. ET AL; Therapy of prostatitis syndrome; Urologe (A) Vol. 40 No. 1 pages 24-28; Springer-Verlag | |
| | | WAGENLEHNER F.M.E. ET AL; Abstract for Therapy of prostatitis syndrome; Urologe (A) Vol. 40 No. 1 pages 24-28; Springer-Verlag | |
| | | DUNN C.J. ET AL; Tamsulosin: A review of its pharmacology and therapeutic efficacy in the management of lower urinary tract symptoms; Drug and Aging (2002) Vol. 19 No. 2 pages 135-161; Adis International Limited | |
| | | D'YAKOV V.V. ET AL; Long term use of Tamsulosin (omnic®) in Patients with Chronic Prostatitis; Urologiya (2002) Vol. 5 pages 10-12; Accession No. Prev200300132038 | |
| | | International Search Report Reference Number PCT/EP2004/003533 | |
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